

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 DEC 2005

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Applicant's or agent's file reference 4FPO-12-11	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/KR2005/000075	International filing date(day/month/year) 10 JANUARY 2005 (10.01.2005)	Priority date (day/month/year) 09 JANUARY 2004 (09.01.2004)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 48/00, A61P 35/00		
Applicant MOGAM BIOTECHNOLOGY RESEARCH INSTITUTE et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 03 AUGUST 2005 (03.08.2005)	Date of completion of this report 16 DECEMBER 2005 (16.12.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LEE, Mi Jeong Telephone No. 82-42-481-5601 

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☒ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☒ the international application as originally filed/furnished

 - ☐ the description:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the claims:
 - pages _____ as originally filed/furnished
 - pages* _____ as amended (together with any statement) under Article 19
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the drawings:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☒ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 21	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1 - 21	NO
Industrial applicability (IA)	Claims	1 - 17	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following document is referred to in this report:

D1: WO 01/19868 A1 (22 Mar. 2001)

1. Novelty

Claims 1–21 of the present invention relate to a therapeutic agent for treatment of cancer comprising human apolipoprotein(a) kringle LK68 or LK8 genes as an effective ingredient, and gene therapy for treating cancer using the same.

D1 discloses that human apolipoprotein(a) kringle LK68 and LK8 inhibit tumor-induced angiogenesis and they can be used as anticancer agents.

D1 differs from the present invention in that the anti-cancer agents are LK68 and LK8 themselves instead of LK68 and LK8 genes.

Therefore, claims 1–21 of the present invention are considered to be novel [Article 33(2) PCT].

2. Inventive Step

Once a protein is known to be effective as a drug, a gene therapy using the genes coding the said protein is easily expected by a man skilled in the art.

Furthermore, the vectors and gene delivering methods described in claims 1–21 show the general state of the art and no surprising effect was reported.

Therefore, the inventive step of claims 1–21 cannot be acknowledged over D1 [Article 33(3) PCT].

3. Industrial Applicability

The subject-matter of claims 1–17 appears to be industrially applicable.

Claims 18–21 relate to a method of therapeutic treatment. Concerning the assessment of the industrial applicability of the subject-matter relating to therapeutic applications, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims [Article 33(4) PCT].

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 2004/073730 A1	02/09/2004	20/02/2004	20/02/2003

Cancer Research, Vol.64, pp.7092-7098 was published on 01.Oct. 2004, i.e. between the priority and filing dates of the present application.

In case the priority of the present application is not valid, these documents are relevant for assessing inventive step of the present invention.

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☒ on paper
- ☒ in electronic form
- c. time of filing/furnishing
- ☒ contained in the international application as filed
- ☒ filed together with the international application in electronic form
- ☐ furnished subsequently to this Authority for the purposes of search and/or examination
- ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed of furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments: